Message

**From:** Cogliano, Vincent [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=51F2736376AC4D32BAD2FE7CFEF2886B-COGLIANO, VINCENT]
**Sent:** 3/11/2016 2:08:29 PM
**To:** Shams, Dahnish [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7037e39bb6341c8850bcdc61bf9d65a-Shams, Dahn]; D'Amico, Louis [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=78a91f83c4414910be286efe02004dbc-D'Amico, Louis J.]; Olden, Kenneth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8979224c77ea4d559f70cab1688f28aa-Olden, Kenneth]; Ross, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98359cd1f66f46ec91d327e99a3c6909-Ross, Mary]; Bussard, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf26b876393e44f38bdd06db02dbbfe5-Bussard, David]; Flowers, Lynn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a4411c874d041b9a8badfc32b91bd70-Flowers, Lynn]; Perovich, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e3c19d7f4db41bfa2477aa27ad83945-Perovich, Gina]; Jones, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eac77fe3b20c4667b8c534c90c15a830-Jones, Samantha]
**Subject:** Re: News Update: EPA Science Adviser Discusses Public Health Role (BNA Report)

I didn't realize that Steve was back in the reporting business. He did Risk Policy Report before going to the NAS and then to consulting many years ago. He was good.

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**From:** Shams, Dahnish
**Sent:** Friday, March 11, 2016 8:56 AM
**To:** Alcala, Cecilia; Alexander, Laurie; Avery, James; Bateson, Thomas; Berner, Ted; Birchfield, Norman; Blessinger, Todd; Boone, Amanda; Brinkerhoff, Chris; Buckley, Barbara; Bussard, David; Cai, Christine; Carmichael, Brenda; Choudhury, Harlal; Cogliano, Vincent; Corona, Elizabeth; Cubbison, Christopher; CURTIS, LUCY; D'Amico, Louis; Deener, Kathleen; Enchill, Kobina; Euling, Susan; Field, Malcolm; Flowers, Lynn; Frithsen, Jeff; Fritz, Jason; Galizia, Audrey; Gamble, Janet; Gatchett, Annette; Gibbons, Catherine; Gift, Jeff; Glenn, Barbara; Grambsch, Anne; Gwinn, Maureen; Hawkins, Belinda; Hogan, Karen; Horansky, Alex; Hotchkiss, Andrew; Hutchins, Debra; Itkin, Cheryl; Jarabek, Annie; Jinot, Jennifer; Johnson, Maureen; Jones, Samantha; Kadry, Abdel-Razak; Keshava, Nagalakshmi; Kopylev, Leonid; Kraft, Andrew; Lee, Janice; Lin, Yu-Sheng; Long, Tom; Luke, April; Makris, Susan; Murphy, Patricia; Nath, Raghu; Nathan, JeffA; Newhouse, Kathleen; Olden, Kenneth; Owens, Beth; Pardo, Larissa; Perovich, Gina; Persad, Amanda; Petersen, Dan; Pratt, Margaret; Preuss, Peter; Radke-Farabaugh, Elizabeth; Reid, Jon; Rieth, Susan; Ross, Christine; Ross, Mary; Rutigliano, Marian; Salazar, Matt; Sams, Reeder; Samuels, Crystal; Sanchez, Yolanda; Sasso, Alan; Schappelle, Seema; Schlosser, Paul; Segal, Deborah; Shams, Dahnish; Shaw, Denice; Slimak, Michael; Spassova, Maria; Suter, Glenn; Troyer, Michael; Vandenberg, John; Vulimiri, Suryanarayana; Walker, Teneille; Walsh, Debra; Weaver, Andre; White, Paul; Woodall, George; Wright, Michael; Zwayer, Bette
**Subject:** News Update: EPA Science Adviser Discusses Public Health Role (BNA Report)

***Risk Assessment***
**EPA Science Adviser Discusses Public Health Role**

*Bloomberg BNA's Steven Gibb interviewed EPA Science Adviser and Deputy Assistant Administrator for the Office of Research and Development Thomas Burke* March 4 on the role he envisions for public health in environmental decision-making. Burke has served as a state regulator and health official, a dean at the Johns Hopkins School of Public Health, and has chaired key risk assessment panels at the National Academies. Below, Bloomberg BNA queries him on his experience at EPA as science adviser and how he has balanced emerging public health crises in Colorado and Michigan with longer-term priorities related to emphasizing public health outcomes in agency risk assessment and decision-making. This interview has been edited for length and clarity.*

**Bloomberg BNA:**
There's a lot of scientific activity and advising always going on at the Environmental Protection Agency. What is your vision for the unique role of the science adviser?

**Thomas Burke:**
It's always evolving. If you've followed the science of the National Academy [NAS] and some of the reports on strengthening science at EPA, there's always been questions about how you organize and assure strong scientific leadership at EPA. I have to say, being in that job now as science adviser with Gina McCarthy and the leadership we have now, it has been an amazing experience. To me it underscores the need for a strong science adviser who also works with and through Office of Research and Development [ORD] to assure the science communication, the science resources but also the forward thinking to keep EPA strong for the future. We need the capacity to respond to things that sometimes are unanticipated like the Gold King Mine and the Flint, Michigan, drinking water crisis. We really need that strong scientific foundation. In terms of scientific activity, as you know through my work on NAS studies and as a state regulator in New Jersey, I've worked very closely with EPA. Still, it is incredible to me how much the agency relies on good strong science to guide decision-making.

**Bloomberg BNA:**
As a public health person do you find that your priorities are set for you because of these emerging crises or do you get a chance to set and advance your own priorities?

**Burke:**
Let's go back to the process of my being invited to be part of the leadership team. I came from being a dean at the Johns Hopkins School Public Health and a health commissioner in a state, but my heart is in environmental science so this is a great blend of things. I think as you look at the kinds of things we face as an agency, it's really the long-term vision articulated by Gina McCarthy that underscores the public health role and the important public health mission of the EPA, whether it be in climate or ozone or drinking water. It's fundamental to what we do. Sure there's that environmental protection aspect but health is really important. I think Gina McCarthy has really underscored that component. For me it's been a joy since the early conversations about my joining EPA that that was embraced. Now we reach out to states and state public health commissioners who take part in our conversations, and we've incorporated their input. My own personal priorities match the long-range vision.

Your question was: how do you balance the demands of emerging issues with the long-range vision which is part of the NAS "Science and Decisions" report that I think brings public health into the risk assessment process. I have to say, because ORD is so strong, and because there are so many good resources there in terms of everything from risk analysis to epidemiology to toxicology, it has been a tremendously rewarding part of my job to keep that long-term vision prominent as we move the agency towards a systems approach. Public health is the ultimate systems approach. We have to address disease but also causal factors and consider things like prevention. I really hate to say it's my vision because it's very much been developed with others at EPA and particularly at ORD.

***"We've seen now for 40 years the futility of chasing individual molecules."***
***Thomas Burke, EPA Science Adviser***

The understanding of the connection between environmental quality and health and underscoring that and providing the science to re-affirm that connection has been part of what scientists at the agency have been doing. If we have a grand vision, which is very much shared with others, it is the problem formulation step that integrates science up front. We think about environmental problems not just at the end of the pipe, and certainly not in terms of just command and control perspectives, but to use public health tools to inform decisions and work towards prevention. Ultimately when there's a better blend of public health and environmental protection it leads to a lot fewer arguments about any specific substance or media-specific regulatory approach.
How is EPA broadening its reliance on epidemiology in the work that it does?

**Burke:**
Traditionally, animal toxicology has won the day in pushing risk assessment, and sometimes we debate dose-response in rodents and haven't made good use of the epidemiological evidence. I'm happy to report that epidemiology is alive and well. It is being brought to the fore on many of the very important public health issues the agency faces. One of the reasons epidemiology is so important is because it's really about understanding the problem you're trying to solve and the many factors that go into that. For our top policy questions—be they climate or energy or exposures—the one-molecule at a time toxicology approach is important for hazard identification. But if we're going to be successful in the end goal of improving public health, epidemiology is going to be really important to that.

If you've followed the formaldehyde report from the NAS, to the evolution of "systematic review" as a tool, I think we've been leaders—along with the National Institute of Environmental Health Sciences [NIEHS] contributions to that—in the consideration of human evidence, combined with emerging new methods in toxicology, all of which illustrate how strong epidemiology has become. This leads to a much better evidence base to support decisions. Epidemiological indicators are very reflective of cumulative risk most of the time. As we move towards understanding environmental and public health risks, epidemiology is essential. I really like being part of that shift and I think you'll see that in our [ORD] integrated science assessments and ultimately in our decision-making.

***"Should we be going after emerging contaminants like the fluorinated compounds one by one?"***
***Thomas Burke, EPA Science Adviser***

**Bloomberg BNA:**
What's on your front burner in terms of risk assessment and science policy?

**Burke:**
We're working on a number of papers in addition to some on the science of responding to emergencies. We have wonderful groups within the agency that are kind of low-profile but that take the long view such as the EPA's Science and Technology Policy Committee. EPA will ultimately be successful if we combine immediate responsiveness with long-term capacity. I would have to say science integration and a systems approach to problem formulation is on my front burner. We're working at risk analysis through a number of different approaches.
Defining what cumulative risk assessment is and what its goals are is a really tough challenge. Is it identifying every potential molecule that contributes to risk and regulating them individually? Or should we refine our problem formulations so we look at things like cardiovascular disease? What are the environmental contributions to it so that we better understand the origins of cardiovascular disorders?

The application of physiologically based pharmacokinetic [PBPK] modeling and new ways to understand and evaluate human exposure are going to be very important. If you look at the longer-range science challenge for long-term decision-making about regulating pesticide or toxic chemical exposures, what is it that we really need to do in terms of respiratory disease or concerns about neurodevelopmental toxicants? I think the cumulative risk assessment approach needs to be considered in a different way. We may need to re-think problem formulation and the collection of evidence. We need to support epidemiology and the human health basis of what we do.

**Bloomberg BNA:**
Pesticide makers have raised concerns that epidemiology—as opposed to animal toxicology—is being used more broadly in EPA pesticide decisions. Will this focus on epidemiology continue during your tenure and beyond?

**Burke:**
I think the nature of the endpoints that we're addressing like neurodevelopmental issues and given the complexity of the risk factors, it will absolutely be essential that we take a public health approach to understanding the relative risks and attributable risks to endpoints of EPA concern. It's going to be informed by toxicology and high-throughput screening of chemicals, but ultimately the validation of what we do is going to be: have we reduced human exposure? And ultimately, are we improving public health?

That's a tough one but frankly I think that's very important to the future of environmental science. It's what the public needs to know and what decision-makers need to know. Some of the new tools we've developed complement epidemiology. One of the big knocks on epidemiology in the past has been that these were studies of opportunity where we had only poor information about the doses of chemicals people were exposed to. But with PBPK modeling and the advancements in our quantitative methods it allows us to revisit epidemiological studies and strengthen our understanding of dose-response relationships. Particularly with some of the creative approaches of our NIEHS/EPA Children's Environmental Health and Disease Prevention Research Centers, we have really been leading the way in the epidemiology of lead, mercury and pesticides and the effects and benefits of reducing those exposures. We can use that work in ways that will be much more protective of public health.

**Bloomberg BNA:**
Do you foresee any advances in cumulative risk assessment [CRA] methods that will improve EPA's long-standing efforts to write CRA guidelines? Or is the agency now emphasizing Health Impact Assessment instead of CRA?

**Burke:**
Health Impact Assessments [HIA] may be the ultimate exercise in cumulative risk because you look at community health endpoints. It involves thinking about everything from drinking water source decisions to construction of new facilities and air quality. I think HIA is a tremendous tool and has a lot in common with public health and with traditional human health risk assessment [HHRA]. We've seen now for 40 years the futility of chasing individual molecules. This is especially true in providing safe drinking water because Flint's now in everyone's consciousness.

As we rethink cumulative risk assessment and problem formulation, we're asking ourselves: should we be going after emerging contaminants like the fluorinated compounds one by one? Or should we be thinking cumulatively in a way that uses a systems approach and perhaps gives us multiple benefits? We should not try to solve this with a toxicology model but instead explore how we prevent exposure to these chemicals as a group. That decision [on fluorinated compounds] may be informed by HIA and ecological risk assessment [ERA].

Going forward I think we'll see the ongoing emergence of three tools: HHRA, HIA and ERA which I've learned so much from in doing the NAS "Science & Decisions"report in terms of problem formulation. I think these will be the ways of approaching environmental science in the future.

**Bloomberg BNA:**
What are the prospects that cancer and noncancer approaches to chemical risks will be integrated at EPA per the recommendation of the panel that you chaired at NAS that wrote the report, "Science & Decisions: Advancing Risk Assessment"?

**Burke:**
Everyone has their own interpretation of what that report means. Initially, a lot of people thought integration means we'll treat substances with a noncancer endpoint just like chemicals that are carcinogens with no allowable exposure levels. But that's really not what was intended. We're moving ahead in very important directions now. As you know, current practice at EPA is to develop "bright lines," or reference doses for chemicals with noncancer health effects. So it's either you are under or over the bright line, and the decision-maker faces a "yes or no" option. But with this approach you don't quantify the risks at various levels. We're not really informed about the magnitude of noncancer risks. So that makes it hard to understand alternatives to certain pesticides and other chemical substances when facing a decision.

This creates all kinds of problems for economists trying to understand the impact of a regulatory approach on the economy or the cost of regulations. We now have much better mathematical approaches to quantify risk through benchmark dose and the quantification of dose approaches very much like we do with the slope of a cancer dose-response curve. This will allow us to better quantify the magnitude of the risk. But more importantly it will help with a public health approach.

For the past 30 years in environmental protection, decision-making has been dominated by carcinogen control. This is just the evolution of the environmental regulatory approach. Thus we have a lot of debate about the reports from theInternational Agency for Research on Cancer and whether a chemical is a carcinogen or not. Somehow we think a non-carcinogen is better than a carcinogen. But I think our knowledge has evolved in public health and toxicology so we're understanding that there's some very important immunological effects, neurodevelopmental effects, and long-term neurological effects that are more sensitive than cancer in terms of protecting the population. We see this now with the heavy metal lead for instance. There's no evidence that there's a safe level of exposure to children. We are moving towards presenting much more robust evidence about these noncancer risks and the full-range of health impacts and evidence. We are making great progress on the quantification of risk to multiple endpoints, emerging toxicology indicators, and human evidence, so it really informs decisions better.

**Bloomberg BNA:**
Does a "war on noncancer" have resonance?

**Burke:**
I'm an epidemiologist, so we look at morbidity and mortality and the things we have to grapple with in our lives and the illnesses that folks we know have. We are all concerned with neurological disease and we're all touched by folks with autoimmune responses. We're all incredibly concerned about effects on the unborn, young children, and neurodevelopmental issues. I think Zika has risen to global consciousness because of the potential impact on the unborn and really the dread of birth defects. Yes cancer will always be an emotional disease. And in terms of public health impact, respiratory disease and other concerns, you think about why people go to the doctor. There's infectious diseases and other types, but certain chronic noncancer diseases need to be part of the equation when making environmental health decisions.

**Bloomberg BNA:**

We understand the company that makes the larvicide "temephos" is no longer supporting its public health use for mosquito-control in standing water. Are you concerned about the loss of public health tools like this in the face of Zika and other potential threats?

**Burke:**
My apologies but I'm not familiar with temephos or the nature of that compound or its health effects. In a more general sense, Zika and the fact that right now we do not have a vaccine, or traditional clinical interventions, really underscores the importance of the environment and environmental controls and pest management.

***"For the past 30 years in environmental protection, decision-making has been dominated by carcinogen control."***
***Thomas Burke, EPA Science Adviser***

I am concerned about this as a public health person who has traveled the world and learned to wear long sleeves in tremendously hot climates and to use repellents. Mosquito-borne illness is a top global concern—just look at malaria. But I am concerned that we need to continue to develop safe alternatives in pest management that protect public health but also don't have collateral health impacts that may be unintended. We have to be very cautious as we move forward with a public health approach not just for Zika, but in making public health trade-offs generally as we think about integrated pest management.

**Bloomberg BNA:**
Any closing thoughts?

**Burke:**
I'm working carefully with my colleagues in ORD and throughout EPA's programs to really think through how to use epidemiology so we can continue to guide EPA science and decision-making. People ask me: why did you leave Hopkins to come to EPA? I think science at EPA has been important throughout the world. I love the fact that I can be a public health professional that pushes for a systems approach to public health in the environmental decision-making process at this agency.
**On July 13, 2015, Administrator McCarthy temporarily delegated authority for the ORD deputy assistant administrator and the EPA science advisor to perform duties delegated to the ORD assistant administrator. This temporary delegation of authority will remain in effect until the Senate confirms a presidentially appointed nominee for assistant administrator for ORD or the president makes a recess appointment to fill the vacant position.*

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